up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent, and the aqueous phase comprising a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier, the dispersion being devoid of additional bactericidal or bacteriostatic preservative agents and causing little or no irritation at the site of injection.

16. (New) The dispersion of claim 15 where the propofol and diluent are present in a ratio of about 1:4 to about 1:0.1 of propofol to diluent.

17. (New) The dispersion of claim 15 where the propofol and amphiphilic agent are present in a ratio of about 1:0.8 to about 1:2.5 of propofol to amphiphilic agent.

18. (New) The dispersion of claim 15 that has a viscosity of from about 0.8 to about 15 centipoise.

19. (New) The dispersion of claim 15 wherein the propofol-soluble diluent is a pharmaceutically acceptable saturated or unsaturated synthetic or natural fatty acid, a triglyceride thereof, or a mixture thereof.

20. (New) The dispersion of claim 15 wherein the propofol-soluble diluent is one or more selected from pharmaceutically acceptable esters or triglycerides of medium chain and/or long chain fatty acids of synthetic or natural origin.

21. (New) The dispersion of claim 15 wherein the propofol-soluble diluent is one or more selected from isopropyl myristate, cholesteryl oleate, ethyl oleate, squalene, squalane, alpha-tocopherol, and Miglyol-810.

22. (New) The dispersion of claim 15 wherein the propofol-soluble diluent is one or more selected from pharmaceutically acceptable natural triglycerides from vegetable or animal sources, pharmaceutically acceptable vegetable oils, and pharmaceutically acceptable omega-3 polyunsaturated fish oils.

23. (New) The diluent of claim 22 wherein the vegetable oil is soybean oil.

24. (New) The dispersion of claim 15 wherein the propofol-soluble diluent is a mixture of medium-chain triglyceride and vegetable oil.

25. (New) The diluent of claim 24 wherein the ratio of medium-chain triglyceride to vegetable oil is from 1:3 to 3:1.

26. (New) The dispersion of claim 15 wherein the water-insoluble matrix consists of a mixture of about 1% to about 15% of propofol, up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent.

27. (New) The dispersion of claim 15 wherein the water-insoluble matrix contains about 2% to about 10% of propofol.

28. (New) The dispersion of claim 15 wherein the surface stabilizing amphiphilic agent is one or more natural or synthetic surface modifiers selected from ionizable or non-ionizable phospholipids or cholesterol or a mixture of these amphiphilic agents.

29. (New) The dispersion of claim 15 wherein the surface stabilizing amphiphilic agent is one or more charged or uncharged phospholipid of natural sources, hydrogenated lecithin, a synthetic phospholipid, or a combination of these surface modifiers, or a combination of these surface modifiers with a poloxamer, a poloxamine or a polyoxyethylene sorbitan ester.

30. (New) The dispersion of claim 15 wherein the surface stabilizing amphiphilic agent is a combination of cholesterol and one or more charged or uncharged phospholipid of natural sources, hydrogenated lecithin, or a synthetic phospholipid.

31. (New) The dispersion of claim 15 wherein the surface stabilizing amphiphilic agent is Lipoid E80, or Lipoid EPC, or Lipoid SPC, or Lipoid SPC-3, or phospholipon-90H or phospholipon-100H.

32. (New) The dispersion of claim 15 wherein the surface stabilizing amphiphilic agent is 1,2-dimristoyl-sn-glycero-3-phosphocholine, or 1,2-dimristoyl-sn-glycero-3-[phospho-rac-(1-glycerol)], or egg lecithin, or egg phosphatidylcholine, or soy phosphatidylcholine, or saturated soy phosphatidylcholine, or soy lecithin, or dimyristoylphosphatidylcholine, or dimyristoylphosphatidylglycerol.

33. (New) The dispersion of claim 15 that has a non-existent or minimum potential for hemolysis of human or animal blood.

34. (New) The dispersion of claim 15 where irritation to the tissues at the site of injection is either non-existent or minimized.

35. (New) The dispersion of claim 15 that elicits an anesthetic or sedation effect in warm-blooded animal and human subjects upon intravenous administration.

36. (New) The dispersion of claim 15 wherein the tonicity modifier is sucrose, dextrose, trehalose, mannitol, lactose, or glycerol.

37. (New) The dispersion of claim 15 wherein the tonicity modifier comprises a mixture of sucrose, dextrose, trehalose, mannitol, lactose, or glycerol.

38. (New) The dispersion of claim 15 that is isotonic with blood.

39. (New) The dispersion of claim 15 that is suitable for intravenous injection.

40. (New) The dispersion of claim 15 that contains a pharmaceutically acceptable water-soluble polyhydroxy additive that provides an osmolality of about 250 to about 700 milliosmolal.

41. (New) The dispersion of claim 15 wherein the osmolality is about 300 to about 500 milliosmolal.

42. (New) The dispersion of claim 15 that has a viscosity from about 2 to about 5 centipoise.

43. (New) A sealed vial containing the dispersion of claim 15.

44. (New) A process for preparing an injectable, stable, sterile, antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm capable of substantially limiting or inhibiting the growth of microorganisms and consisting essentially of about 1% to about 15% of propofol, up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent, and the aqueous phase comprising a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier, the dispersion being devoid of additional bactericidal or bacteriostatic preservative agents and causing little or no irritation at the site of injection comprising preparing a premix of a lipophilic phase and an aqueous phase in which propofol, a propofol-soluble diluent, and an amphiphilic agent are mixed to prepare the lipophilic phase and the aqueous phase comprises a polyhydroxy compound in water, mixing the premix with a high-speed homogenizer under a generally inert atmosphere with the temperature controlled to minimize oxidation, then homogenizing the premix by high pressure homogenization or microfluidization to form a dispersion, then filling the dispersion into glass vials that are purged with a generally inert atmosphere and then sealed with compatible stoppers and seals and steam sterilized.

REMARKS

Reconsideration of this application is requested. Claims 1-13 and 15-44 are active in the application subsequent to entry of this amendment.

Responsive to the requirement for restriction, applicants elect the subject matter of Group I, namely claims 1-12 drawn to compositions.

In addition, applicants have presented new claims 15-44 directed to preferred aspects of the invention and all to elected subject matter, namely injectable stable sterile antimicrobial aqueous dispersions. Please see the attached explanation of the origin for the terminology used in these new claims which explains basis for these claims in the original disclosure.